DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	02/25/2013 - 03/01/2013* FEI NUMBER 3010054268

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: John R. Carson, President-CEO

FIRM NAME	STREET ADDRESS
Home Intensive Care Pharmacy, Inc.	7220 Louis Pasteur Drive Suite 168
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Antonio, TX 78229	Producer of Sterile Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not written and followed.

Specifically, your firm does not have written procedures describing how aseptic operations are performed in ISO 5 and ISO 7 classified areas.

- On 2/25/2013, a pharmacist from your facility wearing a non-sterile lint-free labcoat rested his elbows on the benchtop of one-of-(b)(4) ISO 5 laminar air-flow hoods while preparing an order for Morphine/Bupivacaine, an intrathecal medication used for pain pump sterile administration.
- On 2/25/2013, a pharmacist from your facility had an approximate 1 inch-to-2 inch gap in coverage from his non-sterile lint free labcoat sleeves and his sterile gloves while performing aseptic filling of the same Morphine/Bupivacaine order. Exposed skin from his forearm was visible while he was working inside the ISO 5 laminar air-flow hood.

OBSERVATION 2

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, your firm's gowning requirements described for operators working in ISO 8, ISO 7, and ISO 5 classified areas include a single pair of sterile gloves, a single pair of non-sterile shoe covers, a single non-sterile lint-free lab coat, a single hair net, and a single ear-loop face mask.

- Your firm does not have a written procedure describing the gowning requirements for aseptic operations performed in classified areas of your facility.
- On 2/25/2013, a pharmacist from your firm was performing aseptic filling of Morphine/Bupivacaine Injection inside the ISO 5 laminar air-flow hood wearing the garments described above.
- Exposed skin was observed around the eyes, forehead, and neck for operators processing a sterile drug.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Christopher D. Leach, Investigator
Lucas B. Leake, Investigator

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03/01/2013

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OBSERVATION 3

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, your firm has not evaluated the composition of equipment contact surfaces or the facility layout in order to prevent the contamination of ISO 5, ISO 7, and ISO 8 classified areas used in the production of sterile drug products.

- You (b) (4) ISO 5 laminar air-flow hood workbenches are constructed from particle board with a laminated surface on which sterile drug products are aseptically filled. This was confirmed by your firm's Chief of Staff on 2/26/2013.
- The smoke study conducted by a contracted testing laboratory on December 18th, 2012 for the ISO-5 laminar air-flow hood was not performed during dynamic conditions.
- The pressure differential limits tested by a contracted testing laboratory on December 18th, 2012 for the ISO 5 laminar air-flow hood, the ISO 7 area, and the ISO 8 ANTE room were only tested in static conditions. These pressure limits between classified rooms are not actively monitored by your firm during normal operating conditions according to your firm's Chief of Staff. Your firm has not set limits for pressure differentials between the ISO 7 and ISO 8 classified areas, and during aseptic processing on 2/25/2013 it was observed that the pressure readings of the ISO 7 cleanroom and the adjacent ISO 8 ANTE room showed no apparent difference.
- A spacial gap was observed on 2/25/2013 in the doorway between the ISO 7 cleanroom and ISO 8 ANTE room while an operator was processing a sterile drug product.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, your firm does not have a written procedure describing the rotation of cleaning agents and sporacides used to disinfect the ISO 5 laminar air-flow hood, the ISO 7 classified area, or the ISO 8 ANTE room.

- Your firm did not document an evaluation of the effectiveness of (b) (4) (b) (4) used as the exclusive cleaning agents on the equipment contact surface of the ISO 5 laminar air-flow hood workbench. These products were observed in use on 2/25/2013, and they were observed in storage in the ISO 8 classified Material Wipe-down area.
- Your firm did not document an evaluation of the effectiveness of a (b) (4) (b) (4) used in rotation as cleaning agents on the walls and floors of the ISO 7 classified areas and the ISO 8 classified areas. These products were observed in storage in the ISO 8 classified Material Wipe-down area.

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OBSERVATION 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm does not have a written procedure regarding the performance of environmental monitoring of ISO 5 classified areas used to produce sterile drug products.

- A contract testing laboratory performs viable and non-viable monitoring of all (b)(4) of the ISO 5 laminar air-flow hoods during recertification every (b) (4) only under at rest conditions. The firm has not performed a study in dynamic conditions.
- Your firm does not perform environmental monitoring of ISO 5 classified areas outside of the certification every (b) (4)
- Your firm does not perform any personnel monitoring of those operators working in ISO 5 classified areas during the production of sterile drug products. Your firm's policy states that personnel monitoring is only tested during the (b) (4) media fill qualifications.

OBSERVATION 6

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm has no written procedure or protocol to define how extending the beyond use date of intrathecal drug products from 24 hours to 30 days is validated and what specifications must be met in a stability protocol. Additionally, your firm's management stated that 80% of all compounded drug products are labeled with extended beyond use dates.

- Your firm's pharmacy manager stated that anti-microbial effectiveness testing is not performed by your contract testing laboratory for stability tests of sterile drug products containing preservatives to support your labeled Beyond Use Dates.
- Stability testing in support of extended beyond use dating for intrathecal drug products was inconsistent and does not always include sterility testing.
  a) Stability results dated 2/1/2013 for extended beyond use dates for Bupivacaine 1mg/mL IN PF NS (lot # 01162013-REG) included data for potency/purity, endotoxin, sterility, and particulate matter.
  b) Stability results dated 1/27/2012 for extended beyond use dates for Bupivacaine 5 mg/mLin NaCl (lot # 1442363-n) included data for potency/purity.
  c) Stability results dated 11/17/2011 for extended beyond use dates for Fentanyl 50 mcg/mL PF Inj. (lot # HIC-101211-1me) included data for potency/purity.

OBSERVATION 7

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, your firm's media fill validations conducted for each pharmacist performing aseptic operations do not include all

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sources of potential contamination typical of normal operating conditions.

- Your firm's policy titled, "Employee Qualifications for Sterile Compounding," states that (b) (4) [redacted] Your media fill policy does not address the use of syringes as the finished drug product container, and it does not include all typical manipulations that occur under normal operating conditions--for example the opening and closing of doors between ISO 7 and ISO 8 classified areas during aseptic operations.
- On 2/22/2013 your firm filled an order for (b) (4) bags of Magnesium Sulfate 1gm in 100mL Dextrose 5% with a Beyond Use Date of 5/23/2013, lot # HIC022213-1DC. Operations to include the production of sterile infusion bags are not assessed in your current media fill validations.
- On 2/22/2013 you firm filled an order for (b) syringes of Phenylephrine 0.4mg/mL-single use (10mL) with a Beyond Use Date of 5/23/2013, lot # HIC022213-3DC. Operations to include the production of sterile syringes and a production volume of (b) (4) individual units are not assessed in your current media fill validations.

*** DATES OF INSPECTION:**
02/25/2013(Mon), 02/26/2013(Tue), 02/27/2013(Wed), 03/01/2013(Fri)

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